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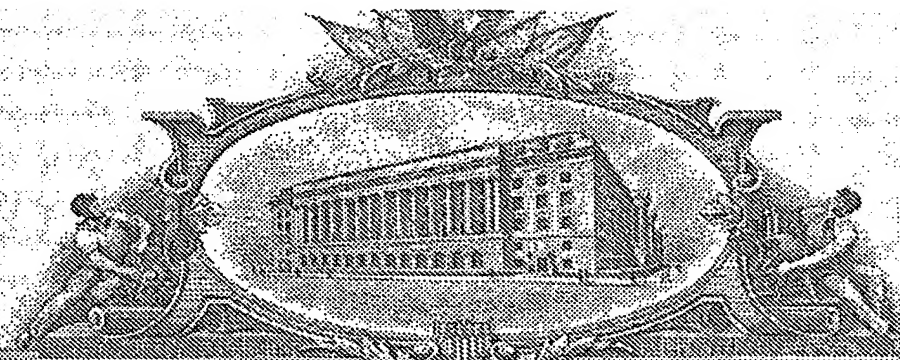
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**APPLICATION NUMBER: 60/508,088**  
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## PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 C.F.R. 1.53 (c).

Docket Number			COR21 PP309		
INVENTOR(S)/APPLICANT(S)					
LAST NAME	FIRST NAME	MIDDLE INITIAL	RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)		
Marcoux Johnson	Michael David	R.	Wyoming, Michigan Granger, Indiana		
TITLE OF THE INVENTION (280 characters max)					
TRANSDERMAL/DRESSING DEVICE WITH EDGE LIFT MINIMIZING HANDLE SYSTEM					
CORRESPONDENCE ADDRESS					
Customer No. 000,277					
STATE	ZIP CODE		COUNTRY		
ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages <u>12</u> <input type="checkbox"/> Small Entity Statement <input checked="" type="checkbox"/> Drawings Number of Sheets <u>1</u> <input checked="" type="checkbox"/> Other (specify) <input checked="" type="checkbox"/> Return Postcard					
METHOD OF PAYMENT (check one)					
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the Provisional filing fees  <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees and credit Deposit Account Number: <u>16-2463</u>			PROVISIONAL FILING FEE AMOUNT (\$160.00)		

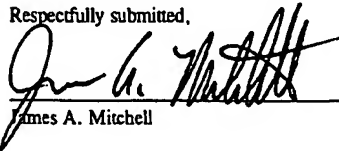
The Invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

Yes, the name of the U.S. Government agency and the Government contract number are:

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Respectfully submitted,



James A. Mitchell

Reg. No. 25 120

October 2, 2003

Date

Additional inventors are being named on separately numbered sheets attached hereto.

***PROVISIONAL APPLICATION FILING ONLY***

TRANSDERMAL/DRESSING DEVICE WITH EDGE LIFT MINIMIZING HANDLE  
SYSTEM

BACKGROUND OF THE INVENTION

- [0001] The present invention relates to adhesive devices used as wound dressings, ingredient delivery devices and IV hold-downs.
- [0002] Wound dressings and IV hold-downs in particular comprise a layer of polymeric film having an adhesive layer on one side thereof which is protected during storage and handling by a release liner. United States Patent Publication 2002/0107466 A1, wholly incorporated herein by reference, discloses such devices which also have a handling member adhered to the non-adhesive coated side of the polymeric film by means of a pressure sensitive adhesive. The pressure sensitive adhesive used between the handle and the polymeric film is less aggressive than the pressure sensitive adhesive used on the underside of the polymeric film, such that once the polymeric film is applied to a patient's skin or mucosa, the handle can be peeled away without peeling the polymeric film away from the patient's skin.
- [0003] Experience has shown that regardless of differences in adhesive strength between the skin or mucosa adhesive and the handle adhesive, there is a tendency for the edge of the polymeric film to lift away from the user's skin or mucosa when the handle member is peeled away from the back of the polymeric film. This same tendency is observed in the wound dressing disclosed in United States Patent 6,169,224, where the handling member is sealed to the polymeric film by a heat activated adhesive.

SUMMARY OF THE INVENTION

- [0004] It has been surprisingly discovered that inadvertent edge release caused by peeling the handle member away from the polymeric film can be minimized by reducing the electrostatic charge buildup in the localized area of the polymeric film beneath the handle, as the handle is peeled away from the film. In various different preferred aspects of the invention, this is accomplished by removing at least a portion of the periphery of the handle layer, or of the adhesive layer on the underside of the handle, so that it does not extend to the periphery of the polymeric film layer upon which the handle layer resides. This reduction in the periphery of

the handle layer minimizes the contact between the adhesive coated surface of the handle and the non-adhesive coated surface of the polymeric film thereby minimizing the electrostatic buildup along the periphery of the polymeric film. Thus, the advantage of having a handle layer is retained while avoiding the electrostatic buildup that contributes to inadvertent edge release.

[0005] In another aspect of the invention, the geometry of the periphery of the handle is designed to reduce the mechanical advantage of the handle against the polymeric film. This mechanical advantage is reduced primarily in two ways. The first is by reducing the surface area of the adhesive coating disposed on the periphery of handle, and the second is by reducing the ability of the handle to act as a lever. Both methods minimize the tendency of the handle to lift the underlying polymeric film away from the patient's skin or mucosa.

[0006] These and other objects, features and advantages of the invention will be more fully understood and appreciated by reference to the written specification and appended drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Fig. 1 is a plan view of a wound dressing, ingredient delivery device, or IV hold-down in accordance with the present invention;

[0008] Fig. 2 is a cross sectional view of the wound dressing, ingredient delivery device, or IV hold-down of Fig. 1, taken along line II-II;

[0009] Fig. 3 is a plan view of a wound dressing, ingredient delivery device, or IV hold-down in accordance with a second embodiment of the present invention; and

[0010] Fig. 4 is a plan view of a wound dressing, ingredient delivery device, or IV hold-down in accordance with a third embodiment of the present invention.

#### BACKGROUND OF THE INVENTION

##### INTRODUCTION

[0011] The term "dressing" as used herein is to be understood to include wound dressings, IV hold-downs and transdermal, dermal, transmucosal and mucosal delivery systems.

[0012] In the preferred embodiment, the basic elements of a dressing in accordance with the present invention comprise a handle 10 having an adhesive coating 20 on the undersurface thereof (Figs. 1-2). Handle 10 is adhered via adhesive layer 20 on handle 10 to the nonadhesive-coated surface of a polymeric film 30. Film 30 has a pressure sensitive adhesive

layer 40 on the undersurface thereof. Adhesive layer 40 is protected during handling and storage by a release liner 50 having a silicone coating layer 51. In use, release liner 50 is removed from the assembled polymeric film 30 and handle 10. Handle 10 is then used to manipulate polymeric film 30 while it is being applied to the patient. Once polymeric film 30 has been applied to the patient, the user grasps handle 10 and peels handle 10 away from the applied polymeric film 30.

[0013] Inadvertent edge release caused by removal of handle 10 is minimized by either reducing the mechanical advantage the periphery of handle 10 has over the periphery of film 30, or reducing the build up of localized electrostatic charge on the periphery of film 30 as the handle is removed. The mechanical advantage is reduced by reducing the ability of handle layer 10 to act as a lever arm, while the electrostatic buildup is reduced by minimizing the contact between adhesive coated surface 20 on the periphery of handle 10 and the underlying non-adhesively coated surface of polymeric film 30.

[0014] As depicted in Fig. 1, handle 10 includes a scalloped periphery or edge 15. Handle 10 is preferably made of a stiffer and generally thicker material than that of polymeric film 30. Typical of such materials are plastic or paper material. Useable plastics include polyesters, polycarbonates, PVC's, polyurethanes, polyethylene vinyl acetates, polyester copolymers, polyethylenes, and polypropylenes. In the preferred embodiment a silicone-coated paper is used.

[0015] The entire undersurface of each handle 10 is coated with an adhesive 20, preferably a pressure sensitive adhesive (Fig. 2) which is moderately aggressive with respect to polymeric film 30, but which does not adhere or adheres less aggressively to either the silicone coating 51 on release liner 50 or to human skin. In this way, a user can readily fold back an end portion of release liner 50 to expose an end of handle 10 and the exposed end can then be used to peel film 30 away from release liner 50. The adhesive of layer 20 is "moderately aggressive" in that handle 10 remains attached to polymeric film 30 when it is peeled away from release liner 50 and while it is being handled and applied to the patient's skin. However, adhesive 20 is less aggressive with respect to its adhesion to polymeric film 30 than is the adhesion of layer 40 on the undersurface of polymeric film 30 toward human skin or mucosa. As a result, handle 10 can be peeled away from polymeric film 30, once film 30 is applied to the patient.

[0016] One type of adhesive which we have found useful for layer 20 on the undersurface of handle 10 is a low tack removable acrylate-based adhesive with a peel adhesive level of approximately three ounces. Other useful adhesives include, but are not limited to, silicone, urethane, synthetic rubber and natural rubber. Adhesives of this type can be formulated to have essentially no or very little adhesion to the human skin or to the silicone coating 51 on the release liner 50, but still adhere firmly but releasably to film 30.

[0017] Polymeric film 30 is preferably comprised of any breathable and waterproof material. In the preferred embodiment, a polymeric film on the order of from about 0.5 to about 4 mils (0.0005 to 0.004 inches) is preferred. The film is preferably very flexible, allowing it to conform readily to the patient's skin or mucosa. The film must have sufficient strength to afford resistance to damage in handling and in use. It also preferably allows the passage of oxygen, thereby allowing the skin or mucosa to breathe. The polymeric film material preferably is a polyurethane film such as a Pebax® film (MediFilm 810, 2 mils, Mylan). Additionally, copolymers of polyethylene and vinyl acetate are also preferable.

[0018] The adhesive layer 40 may be any adhesive that bonds well to skin or mucosa. Preferably, a pressure sensitive adhesive is used. A type of adhesive found useful for adhesive layer 40 is a permanent acrylate-based pressure sensitive adhesive designed for skin, with a peel adhesion level of approximately 50 ounces. Other useful adhesives include, but are not limited to, silicone, urethane, synthetic rubber and natural rubber. Such adhesives can be formulated to adhere releasably to the silicone-coated surface 51 of release liner 50. At the same time, they can be formulated to adhere firmly to the patient's skin or mucosa such that polymeric film 30 will not peel away unless someone intends to do so. For example, one can use an acrylate derivative adhesive such as copolymers of alkyl acrylate/vinyl acetate containing -OH or/and -COOH functional groups, or hydrophobic styrenic rubber polymer or PIB containing 1 to 20% hydroattractants such as PVP, PVA, and cellulose derivatives such as Duro-Tak 87-2516 (National Starch), and PIB containing 20% Kollidon® CL-M (BASF).

[0019] The entire assembly of handle 10, adhesive layer 20, polymeric film 30 and adhesive layer 40 is releasably adhered to release liner 50. Release liner 50 may be comprised of any material that will releasably adhere adhesive layer 40. However, in the preferred embodiment, release liner 50 is a paper material with a silicone coating 51 on the top surface thereof.



#### EDGE GEOMETRY OF HANDLE 10

[0020] The very properties of polymeric film 30 which make it desirable in use make it difficult to handle in application. Edge release typically occurs with these systems when handle 10 is removed from polymeric film layer 30. The generally thicker material of handle 10 creates a lever arm out of handle 10 when handle 10 is being peeled off of film 30. This lever arm created by handle 10 acts to pry up film 30 from the patient's skin. If this force is great enough the edge of film 30 can separate from the patient's skin (e.g., edge release occurs). In general, as the stiffness of the material of handle 10 increases, the less flexible it becomes. The less flexible the handle becomes, the longer the lever arm becomes and this in turn creates higher forces which act upon film layer 30 causing more significant edge release. In addition, it is believed that as handle 10 is removed from polymeric film layer 30, it causes an electrostatic buildup in film layer 30, which contributes to the tendency of the edge of film 30 to release from and be pulled away from a patient's skin or mucosa. Therefore, the properties that make handle 30 useful, namely its stiffness, also create edge release.

[0021] Although not wishing to be bound by theory, it is believed that removing a portion of handle 10, or its underlying adhesive layer 20, from over at least a portion of the edge area of film layer 30 helps to minimize edge release in three ways:

[0022] 1. less adhesive contact area means handle 10 can be removed more easily;

[0023] 2. reducing the ability of handle 10 to act as a lifting lever relative to film 30, at least when a portion of the handle per se is removed; and

[0024] 3. minimizing the localized electrostatic build up at the periphery of film 30 when handle 10 is peeled from film 30, by moving the periphery of handle 30 away from the edge of film 30.

[0025] One way to move at least a portion of the edge of said handle away from the periphery of said polymeric film is to pattern the handle layer with a scalloped pattern as shown in Figs. 1 and 2. In this embodiment, the scalloping extends around the entire perimeter of handle 10. The scalloped edge reduces the mechanical advantage of handle 10 primarily in two ways. The first is by reducing the surface area of adhesive coating 20 disposed on the periphery of handle 10, and the second is by reducing the ability of handle 10 to act as a lever. In the first mode, a portion of the periphery of handle 10 is removed resulting in scalloped edge 15. Simultaneous

to this removal of a portion of handle 10 is the removal of a corresponding portion of adhesive coating 20 attached thereto. This removal of adhesive 20 on the periphery of handle 10 reduces the upward force exerted on the periphery of polymeric film 30 by adhesive coating 20 during its removal. Reducing the upward force exerted on the periphery of polymeric film 30 reduces edge lift. In the second mode, scalloped edge 15 reduces the ability of the generally thicker material of handle 10 to act as a lever arm.

[0026] When the peripheral interaction between adhesive layer 20 and polymeric film 30 is removed, the localized electrostatic buildup on film 30 is also reduced. This is because the interaction between adhesive layer 20 and film layer 30, during their separation, causes the electrostatic buildup. The removal of a portion of the peripheral edge of handle 10, and subsequently adhesive layer 20, or the removal of some of the adhesive at the edges of handle 10 minimizes the electrostatic buildup on the peripheral edge of polymeric film 30 by removing this interaction and therefore, reduces edge lift.

[0027] The scalloped edge (15) of handle 10 is depicted in Fig. 1 as having a wave like or sinusoidal like pattern, leaving projecting portions 16 extending to the edge of film layer 30. Other geometrical forms may be used which reduce the interaction between the periphery of handle 10 and the periphery of film 30. While a handle could be made that simply does not extend to the edge of film layer 30, thereby reducing edge lift, the scalloped pattern has the advantage of having end portions 16 that extend to the edge of film 30. End portions 16 act to support thin film 30 and keep it from folding over onto itself during application. Therefore, scalloped edge 15 retains the benefits of a handle layer (e.g., ease of application) while minimizing the negative effects of a handle layer (e.g., edge lift).

[0028] In the Fig. 3 embodiment, the edge portion of handle 10 along two opposite sides thereof, preferably the longest sides, have been substantially removed as a continuous, uninterrupted strip. This leaves the longest edge portions 31 of polymeric film but retains a portion of handle 10 along two other sides which extends to the film periphery sides to support film 30 during application. Preferably, only the central portion of the edge of handle 10 is removed, such that end or corner portions 11 of handle 10 extend out to the edges or corners to give stability. The Fig. 4 embodiment is similar to the Fig. 3 version, but also incorporates

a window of removed handle material which is centrally located on the dressing, leaving the central portion 32 of film 30 also exposed.

[0029] Although only a few preferred embodiments have been shown and described it is envisioned that there are numerous geometrical patterns that may be used. Additionally, there are supplementary methods which can be combined with the various edge geometries for reducing the edge lift even further. For example, the preferred embodiment may include additional features such as texturing handle 10, texturing adhesive layer 20, texturing polymeric film layer 30 and/or using an anti-static ingredient in one of, the adhesive coating on the underside of the polymeric film, or on the upper or lower surface of the polymeric film itself. Additionally, texturing may be done by piercing slots, placing pin holes, knurling, embossing or debossing, or creating a relatively rough surface on handle 10.

#### APPLICABILITY TO VARIOUS TYPES OF DEVICES

[0030] While the embodiments described above are wound dressings or IV hold-down devices, the various aspects of the present invention are also applicable to devices designed to deliver active ingredients to or through the dermal or mucosal layers. Such delivery systems typically deliver the active via a gel-modulated system, membrane modulated system, or an adhesive modulated system. All of the embodiments of Figs. 1-4 can be made to be ingredient delivery devices by incorporating an active ingredient into adhesive layer 40, for example.

#### CONCLUSION

[0031] The embodiments described above minimize the problem of edge release which typically occurs in adhesive devices used as wound dressings, ingredient delivery devices and IV hold-downs. Of course it is understood that the foregoing are preferred embodiments and changes and variations can be made without departing from the spirit and broader aspects of the invention, as defined in the appended claims, which are to be interpreted in accordance with the principles of patent law, including the Doctrine of Equivalents.

The invention claimed is:

1. A method of minimizing edge release in wound dressings, ingredient delivery devices and IV hold-downs which incorporate a handle layer to assist in their application, wherein the removal of the handle layer, after application of the device to the patient, initiates the edge release, said method comprising:

providing a handle having a first side and a periphery;

applying a first adhesive layer on at least a portion of said first side of said handle;

providing a polymeric film layer including a first side, a second side and a periphery;

applying a second adhesive layer to at least a portion of said first side of the polymeric film layer, said handle being adhered to said second side of the polymeric film layer via said first adhesive layer;

configuring one of said handle, including said first adhesive layer, or said first adhesive layer itself, such that only a portion of the periphery of said handle or said first adhesive layer extends to the periphery of the polymeric film layer, leaving a portion of said periphery of said handle recessed away from said periphery of said polymeric film layer.

2. The method according to claim 1 wherein:

one of the periphery of said handle or said first adhesive layer thereon is fashioned in a repeating pattern with only a portion of each repeated pattern extending to said periphery of said polymeric film layer.

3. The method according to claim 2 wherein:

the shape of said repeating pattern is scalloped.

4. The method according to claim 1 wherein:

at least a continuous, substantial portion of at least one of a plurality of sides of the periphery of one of said handle or said first adhesive layer is configured such that it does not extend to the periphery of said polymeric film layer.

5. The method of claim 4 in which said continuous substantial edge portion is centrally located between the ends of said side such that the end portions of said side extend to said periphery of said polymeric film to give stability to the corners thereof.
6. The method according to claim 4 wherein:  
said handle is further provided a central opening.
7. The method according to claim 1 wherein at least a continuous, substantial portion of at least two opposite sides of the periphery of handle or said first adhesive layer is configured such that it does not extend to the periphery of the corresponding opposite sides of said polymeric film layer.
8. The method of claim 7 in which said continuous substantial edge portions are centrally located between the ends of said opposite sides such that the end portions of said sides extend to said periphery of said polymeric film to give stability to the corners thereof.
9. The method according to claim 6 wherein:  
said handle is further provided a central opening.
10. The method of any of claims 1-9 in which said configuring step is performed on said handle prior to application of said first adhesive layer.
11. The method of any of claims 1-9 in which said configuring step is performed only on said first adhesive layer.
12. A wound dressing, ingredient delivery device or IV hold-down comprising:  
a handle having a first side and a periphery;  
a first adhesive layer coating at least a portion of said first side of said handle;  
a polymeric film layer including a first side, a second side and a periphery;

a second adhesive layer coating at least a portion of said first side of said polymeric film layer, said handle being adhered to said second side of the polymeric film layer via said first adhesive layer;

wherein a portion of the periphery of one of said handle, including said first adhesive layer, or a portion only of said first adhesive layer, does not extend to said periphery of said polymeric film layer.

13. The device according to claim 12 wherein:

the periphery of one of said handle or said first adhesive layer is fashioned in a repeating pattern with only a portion of each repeated pattern extending to said periphery of said polymeric film layer.

14. The device according to claim 13 wherein:

the shape of said repeating pattern is scalloped.

15. The device according to claim 12 wherein:

at least a continuous substantial portion of at least one of a plurality of sides of the periphery of one of said handle or said first adhesive layer does not extend to the periphery of said polymeric film layer.

16. The device of claim 15 in which said continuous substantial edge portion is centrally located between the ends of said side such that the end portions of said side extend to said periphery of said polymeric film to give stability to the corners thereof.

17. The device according to claim 15 wherein:

said handle further includes a central opening.

18. The device according to claim 10 wherein at least a continuous, substantial portion of at least two opposite sides of the periphery of one of said handle or said first adhesive layer does not extend to the periphery of the corresponding opposite sides of said polymeric film layer.

19. The device of claim 18 in which said continuous substantial edge portions are centrally located between the ends of said opposite sides such that the end portions of said sides extend to said periphery of said polymeric film to give stability to the corners thereof.
20. The device according to claim 19 wherein:  
said handle further includes a central opening.
21. The device of any of claims 12-20 in which said handle, including its underlying first adhesive layer, is so configured.
22. The device of any of claims 12-20 in which only said first adhesive layer is so configured.

## TRANSDERMAL/DRESSING DEVICE WITH EDGE LIFT MINIMIZING HANDLE SYSTEM

### ABSTRACT

An adhesive device used as a wound dressing, ingredient delivery device or IV hold-down is disclosed. Inadvertent edge release of these devices along the periphery of the polymeric film layer occurs when the handling layer, which is adhered to the polymeric film layer, is removed after application of the polymeric film layer to the patient. The geometry of the periphery of the handling layer of the device is designed to reduce this inadvertent edge release by 1) reducing the electrostatic buildup along the periphery of the polymeric film; and 2) reducing the mechanical advantage of the handling layer against the polymeric film.



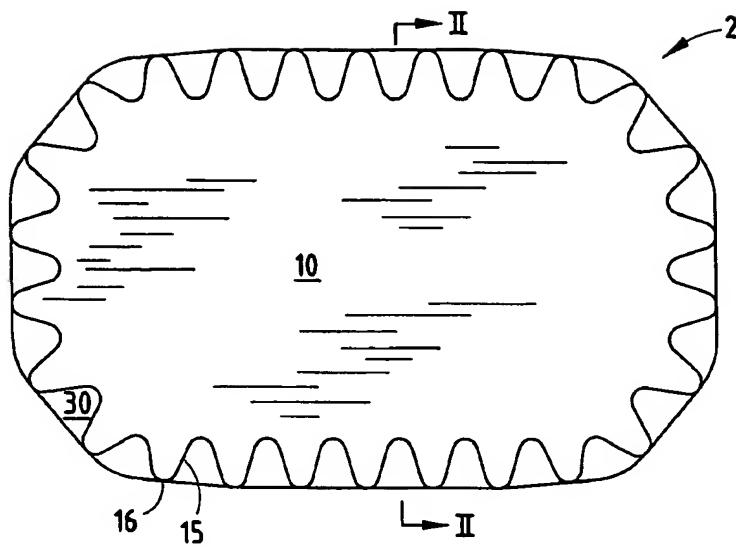


FIG. 1

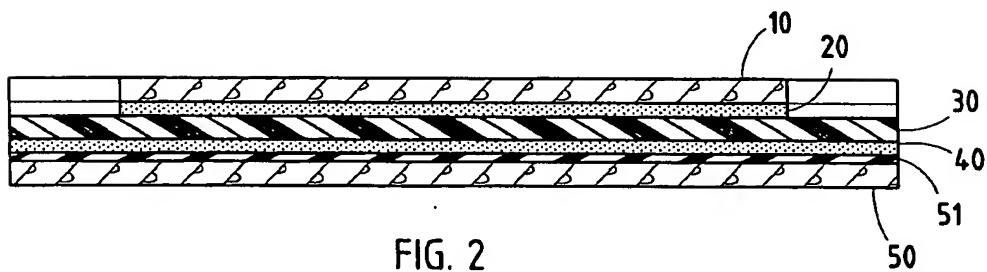


FIG. 2

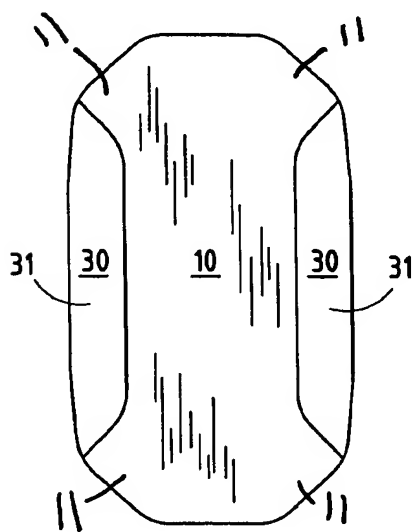


FIG. 3

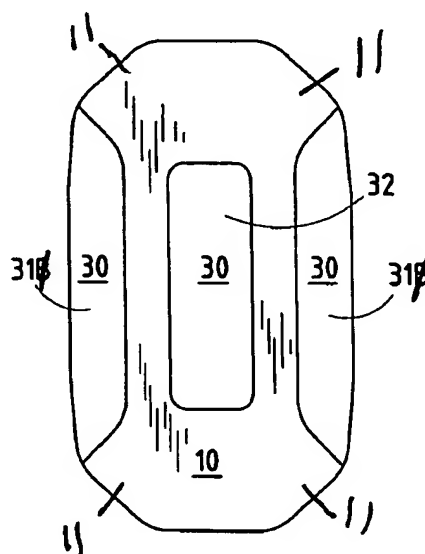


FIG. 4